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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to inferior vena cava ("IVC") filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard"). Bard has filed a motion to exclude the opinions of Dr. Darren Hurst. Doc. 7302. The motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court will deny the motion.

I. Background.

The IVC is a large vein that returns blood to the heart from the lower body. IVC filters are small metal devices implanted in the IVC to catch blood clots before they reach the heart and lungs. This MDL involves seven different versions of Bard IVC filters – the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

Each Plaintiff in this MDL was implanted with a Bard filter and claims it is defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt, perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall complication rates for Bard filters are comparable to those of other IVC filters and that the medical community is aware of the risks associated with IVC filters.

Plaintiffs have identified Dr. Hurst, an interventional radiologist, as an expert witness on various issues in each of the five cases selected for bellwether trials. He has prepared case-specific reports that share certain opinions in common. Doc. 7306. Defendants ask the Court to exclude three categories of opinions: (1) Bard filters have higher complication rates than other filters and an "unacceptable risk" of caudal migration; (2) Bard ignored safety signals, failed to perform additional studies, and misrepresented the safety and performance of its filters; and (3) Bard failed to communicate to doctors that the Meridian filter should be used instead of the G2X or Eclipse. Doc. 7302 at 2.[1] The Court will address each category.[2]

II. Legal Standard.

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony has the ultimate burden of showing that the expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). But the trial court acts as a

[1] Page citations are to the numbers placed at the top of each page by the Court's electronic filing system.

[2] The bellwether cases are those brought by Plaintiffs Sherr-Una Booker, Lisa Hyde, Doris Jones, Carol Kruse, and Debra Mulkey. In moving to exclude Dr. Hurst's opinions, Defendants cite to his reports in the Mulkey, Jones, and Hyde cases. Docs. 7306, 7306-4, 7306-5.

gatekeeper to assure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702's requirements, and the court's gatekeeping role, apply to all expert testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

III. Discussion.

A. Higher Complication Rates and "Unacceptable Risk" of Migration.

Dr. Hurst is a full time physician who received fellowship training in the field of interventional radiology at the University of Michigan Medical Center. Doc. 7306 at 4, 23. He has been the chief of vascular and interventional radiology for St. Elizabeth Health System in northern Kentucky for nearly 15 years, and serves the greater Cincinnati area through his private medical practice. *Id.* He is board certified in both general diagnostic radiology and specialized interventional radiology. *Id.* at 25. He regularly implants and removes IVC filters as part of his clinical practice, including filters manufactured by Bard. *Id.* at 4. He states that he is familiar with the medical literature concerning IVC filter issues, including filter complications and the risks and benefits associated with the devices. *Id.*

In each bellwether case, Dr. Hurst opines that Bard failed to notify the implanting physician of the "higher complication rates associated with the Recovery, G2, and Eclipse filters in comparison to the original predicate device, the Simon Nitinol Filter, and competitor filters." *See, e.g.*, Doc 7306 at 10. Dr. Hurst also opines that "Bard's own internal risk analysis deemed the G2 filter . . . to pose an 'unacceptable risk' of caudal migration." *Id.* at 11. Defendants contend that Dr. Hurst is not qualified to opine that their filters had higher complication rates than other filters or posed an "unacceptable risk" of caudal migration. Doc. 7302 at 4-7.

The Court concludes that the admissibility of such testimony will depend on the manner in which it is given. Dr. Hurst's reports state that physicians reasonably expect medical device manufacturers such as Bard to design, test, manufacture, warn, and

market in a manner that will enable the physicians to select appropriate IVC filters and make correct therapeutic decisions. Doc. 7306 at 8. He states that patients reasonably expect sufficient information to make an informed decision. *Id.* Dr. Hurst quotes the AMA Code of Medical Ethics on informed consent to support these assertions. *Id.* at 9. As an experienced interventional radiologist with years of practice, Dr. Hurst clearly is qualified to opine about the information physicians and patients need and expect when making decisions about the use of IVC filters.

But the precise intent of Dr. Hurst's statement that "Bard failed to notify operating physicians and the implanted patients of the much higher complication rates associated" with its filters (*id.* at 10), and that the G2 filter posed an "unacceptable risk" of caudal migration (*id.* at 11), is not clear. He could be stating that he has learned from other sources that Bard filters have higher complication rates and unacceptable risks of caudal migration, and, in his opinion as a practicing interventional radiologist, these facts, if true, should have been disclosed by Defendants. Such an opinion would fall within the area of his expertise and would be based on his years of experience as a physician, and would be admissible under Rule 702.

Alternatively, Dr. Hurst could be opining that Bard filters have higher complication rates than other IVC filters and have unacceptable risks of caudal migration. The Court is not persuaded that such an opinion would be admissible under Rule 702.

1. Higher Complication Rates.

Dr. Hurst has not conducted any study of IVC filter complication rates. He states that his opinions are based on personal experience with IVC filters, in combination with his "education and training in the field of medicine, and specifically the field of Vascular and Interventional Radiology[.]" Doc. 7306 at 4. But he does not state that he has collected clinical data from his personal cases that reveal IVC filter complication rates, nor that his education and training revealed anything about such rates. He also states that his opinion is "based on discussions with other physicians in [his] region and area, attendance at national meetings and discussions that were ongoing at the time as well[.]"

Doc. 7811 at 5 (quoting Ex. 2 at 52:12-24). But he cites no studies or data that were addressed in these discussions or meetings.

In short, Dr. Hurst provides no information from which the Court can conclude that his own experiences or training as a physician, or his own discussions with other doctors, provide "sufficient facts and data" to support an opinion on Bard filter complication rates. Fed. R. Evid. 702(b). Nor has he identified any "reliable principles and methods" he used in forming opinions from these sources. *Id.*, 702(c).

Dr. Hurst did testify that he reviewed a number of medical articles regarding IVC filter complication rates, and he focused particularly on the Deso article, which conducted a literature search regarding complications associated with various IVC filter designs. Doc. 7302-2.[3] But even if these articles suggest that Bard filters have higher complication rates than other filters, Dr. Hurst does not claim to have taken any steps to verify their conclusions, and merely restating those conclusions does not constitute a reliable basis for rendering an expert opinion under Rule 702. Dr. Hurst cannot simply repeat the opinions of others as his own when he has done nothing to verify the accuracy of the opinions. *See In re Matter of Complaint of Ingram Barge Co.*, 2016 WL 4366509, at *4 (N.D. Ill. Aug. 16, 2016) ("[The expert's] opinions . . . do not rely 'in part' on the purported expertise of other testifying experts. Rather, [the expert] repeats and concurs with their opinions, without additional analysis. The Court does not need an expert to reiterate other experts' testimony.").

2. Unacceptable Risk.

The opinion that the G2 filter poses an "unacceptable risk" of caudal migration is based on a Bard internal document, as Dr. Hurst notes. *See* Doc 7306 at 11. A report titled "G2 Caudal Migration Update" prepared by Bard product quality engineer Natalie Wong states that in certain circumstances the G2 filter had an "[u]nacceptable risk" of caudal migration per Bard's failure modes and effects analysis. *See* Doc. 7825 at 21.

[3] The article is "Evidence-Based Evaluation of [IVC] Filter Complications Based on Filter Type," co-authored by Drs. Steven Deso, Ibrahim Idakoji, and William Kuo, and published in *Seminars in Interventional Radiology* (Vol. 33 at 93-100, No. 2/2016).

Dr. Hurst has testified that he relied in part on the "Wong evaluation of the G2 caudal migration from the [Bard] internal documents." Doc. 7306-1 at 4-5 (Dep. Tr. 254:24-255:1).

Again, however, Dr. Hurst does not identify any steps he has taken to verify the conclusion in the Wong report. Nor does he identify the person or entity to whom the risk he mentions is unacceptable – physicians, patients, medical manufacturers, or the FDA. Dr. Hurst could opine, as a treating physician who must make decisions about IVC filter use, that Bard should have disclosed any risks it found in its products that would be unacceptable to doctors and patients. But he cannot opine that Bard filters present an unacceptable risk unless that opinion is based on sufficient facts and data he has identified, to which he has applied reliable principles and methods. Fed. R. Evid. 702(b), (c). Merely repeating conclusions of the Wong report as his own opinion does not meet this requirement.

3. Conclusion.

Dr. Hurst can testify that if Bard IVC filters had higher complication rates and unacceptable risks of caudal migration, then, in his opinion as a practicing interventional radiologist, those facts should have been disclosed by Defendants. But he cannot present an expert opinion that Bard IVC filters did in fact have higher complication rates and unacceptable risks of caudal migration without satisfying the reliability requirements of Rule 702. He has not done so in his report or deposition testimony.

B. Safety Signals, Additional Studies, and Representations About Filters.

Dr. Hurst renders several opinions about what Bard knew, did, or failed to do. He opines, for example, that Bard ignored early safety signals, chose not to perform additional studies, and falsely represented improvements in newer generation filters in its marketing materials. Doc. 7302 at 7-8; *see* Doc. 7306 at 10-12 (Opinions 4(d)(ii), (v), and (vi)).

The Court is not persuaded that Dr. Hurst is qualified to opine about Bard's internal knowledge, its internal testing and development practices, or the truthfulness of

its representations as a general matter. Plaintiffs do not suggest that Dr. Hurst has ever worked for a medical product manufacturer or the FDA, that he has expertise in internal corporate information gathering or decision making, or that he is trained in the design, testing, or labeling of medical devices. Plaintiffs have identified no basis upon which Dr. Hurst can render expert opinions about what happened internally at Bard – what it knew, what it did, or what it failed to do in the development and marketing of its IVC filters. Nor have Plaintiffs shown that Dr. Hurst had sufficient facts or data to form reliable opinions about the inner workings at Bard. As Defendants note, he reviewed only 24 internal Bard emails and documents.

As a practicing interventional radiologist, Dr. Hurst can testify about what a physician would expect to receive from Bard. But he cannot state opinions about what was known within Bard or what was or was not done within Bard. Such opinions are outside the realm of his expertise and are not supported by sufficient facts and data or evaluated through reliable principles and methods. Fed. R. Evid. 702(b), (c).

C. Bard's Lack of Communications Regarding the Meridian Filter.

Defendants ask the Court to preclude Dr. Hurst from opining that Bard failed to communicate to the implanting physicians in the Mulkey, Jones, and Hyde cases that the Meridian filter should be used instead of the Eclipse or G2X filters. Doc. 7302 at 10 (citing Doc. 7306 at 11-12). Plaintiffs agree that Dr. Hurst can render no such opinion in the Jones and Hyde cases because the Meridian filter was not on the market when these plaintiffs received their Bard filter implants. Doc. 7811 at 2, 9 n.2.

With respect to the Mulkey case, Defendants argue that Dr. Hurst's opinion is speculative because he does not know what information Bard provided to Mulkey's implanting physician or how the Meridian filter compares clinically to the Eclipse. Docs. 7302 at 10-11; 8223 at 7. This argument appears to be well taken. In addition to the fact that Dr. Hurst does not know what information Mulkey's physician received, Dr. Hurst has never implanted a Meridian filter and he identifies no study or data to suggest that the Meridian has fewer complications than the Eclipse. The Court

concludes, however, that a final ruling on this issue should await trial in the Mulkey case. The Court will then have the benefit of earlier bellwether trials and possibly testimony from Dr. Hurst himself.

D. Reasonable Expectations and Informed Consent.

Defendants' motion does not seek to exclude Dr. Hurst's opinions regarding what reasonable physicians and patients expect from medical device manufacturers, or his opinions about how the duty of informed consent bears on these expectations. Plaintiffs nevertheless argue in their response that these opinions will assist the jury. Doc. 7811 at 10. In their reply, Defendants disagree and argue that these opinions are inadmissible.

The Court will not grant relief on an argument not made in Defendants' motion, but because the issue has been addressed by the parties and will be relevant at trial, the Court confirms the views set forth above. Dr. Hurst's training and years of experience as an interventional radiologist qualifies him to opine on these subjects. Although a final decision must await trial, the Court also concludes that such testimony likely will be relevant to the jury's consideration of whether Defendants failed to warn Plaintiffs and whether that failure caused Plaintiffs' injuries.

IT IS ORDERED that Defendants' motion to exclude the opinions of Dr. Darren Hurst (Doc. 7302) is **granted in part and denied in part**. The motion is granted as follows: Dr. Hurst cannot (1) opine that Bard filters have higher complication rates than other IVC filters and have unacceptable risks of caudal migration, or (2) render opinions about Bard's internal knowledge, its internal testing and development practices, or the truthfulness of its representations in general.

Dated this 22nd day of January, 2018.

David G. Campbell
United States District Judge